Chapter 1
Ethical Medical Data Donation: A Pressing Issue

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Abstract While donation schemes with dedicated regulatory frameworks have made it relatively easy to donate blood, organs or tissue, it is virtually impossible to donate one's own medical data. The lack of appropriate framework to govern such data donation makes it practically difficult to give away one's data, even when this would be within the current limits of the law. Arguments for facilitation of such a process have been advanced but so far have not been implemented. Discussions on the ethics of using medical data tend to take a system-centric perspective and focus on what researchers and the health service may or may not do with data that are placed within their trust. Rarely, if ever, is the question of the data subjects preferences addressed beyond practical matters of obtaining valid consent. This constitutes an important omission in the ethical debate, which this volume seeks to address.

1.1 Background

Donation has become a key concept in many areas of medicine, where it is now deeply engrained in everyday clinical practice, as well as in medical research. When physical donations are concerned, their importance of such medical donations is no

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longer questioned, and increasingly medical governance systems are shifting from voluntary, opt-in models to opt-out schemes. Most recently, and in light of the introduction of the General Data Protection Regulation in Europe (GDPR), discussions have centered on the use of medical records for research purposes without the need for individual consent procedures, which are perceived as a significant obstacle to the advancement of medical insight and development of new treatments (Mann et al. 2016).

While donation schemes with dedicated regulatory frameworks have made it relatively easy to donate blood, organs or tissue, it is virtually impossible to donate one's own medical data. The lack of appropriate framework to govern such data donation makes it practically difficult to give away one's data, even when this would be within the current limits of the law. Arguments for facilitation of such a process have been advanced but so far have not been implemented (Shaw et al. 2016). Researchers are increasingly encouraged – and sometimes even required – to share their data in the name of science, and yet individuals cannot easily make their data available for scientific research purposes. This presents an ethically unjustifiable asymmetry in the biomedical research context: first, these datasets are of enormous importance for improvements in population health; and second, the difficulty infringes the autonomous decisions of many individuals who wish to contribute to the advancement of medical knowledge by making available their medical information.

Competing tensions on data control and ownership, respect of individual rights and consent, limited technical understanding, and the lack of adequate frameworks for coordination and ethical governance pose serious challenges to the donation of data and risk undermining its huge potential. The effect of the GDPR on medical data use is still uncertain, but some are concerned that it might be a serious impediment to scientific research and the re-use of data. Guidance to meet these challenges is urgently needed to ensure respect of users' individual rights and consent, foster transparency and trust, as well as harness the value of data to spur scientific research, public debate, private and public wellbeing.

The issue of systematically allowing private individuals to volunteer their medical data for research purposes has not yet been addressed in academic or popular literature, where emphasis has been placed mostly on data sharing between researchers, or on donations by private corporations in the context of data philanthropy (Taddeo 2016). However, empirical studies suggest that there is great willingness to allow medical data re-use on certain conditions, although medical donation schemes remain to this day largely limited to physical donations, such as organs, tissue or blood (Steinsbekk et al. 2013). There is significant scope to learn from posthumous physical donation schemes (Richardson and Hurwitz 1995), but the ethical and governance frameworks cannot be applied directly to data donation due to the specific characteristics of medical data. There is thus a need to develop a dedicated ethical code for posthumous data donation.

1.2   Current Debates

Discussions on the ethics of using medical data tend to take a system-centric perspective and focus on what researchers and the health service may or may not do with data that are placed within their trust. Rarely, if ever, is the question of the data subjects' preferences addressed beyond practical matters of obtaining valid consent. This constitutes an important omission in the ethical debate. The lack of comprehensive coverage of the topic of medical data donation has led the Digital Ethics Lab at the Oxford Internet Institute at the University of Oxford, to develop an ethical code for posthumous medical data donation (PMDD), in collaboration with Microsoft Research.

Two workshops were held in October 2017 and April 2018 to address the ethics of medical data donation. The aim of these workshops was to gather insight from academia, government, and industry in order to assess the risks and opportunities of PMDD. Participants came from diverse disciplines, and contributions covered topics related to the ethics of data donation, the legal and regulatory challenges posed by the donation of personal medical data, and current and future projects and collaborations in medical data donation.

Some key challenges were identified: trust, data quality, social values affecting the willingness to share data, impediments to corporate data sharing, and concerns around justice and inclusion. It was suggested to make health data sharing cases more tangible, by giving concrete examples of benefits for the stakeholders involved and practical information about the use and re-use of donated data. This was seen as potentially contributing to the removal of barriers to data donation by fostering a greater understanding of the process, including the risks involved. In addition, inclusion was mentioned as a key theme for further investigation, as current data donation projects such as the PGP UK are relatively exclusive, because they facilitate participation only by highly-educated, highly-engaged individuals ("Personal Genome Project: United Kingdom" 2018).

The ideas presented at the workshops and the discussions that ensued informed the development of the ethical code for PMDD presented in this volume. Many more ideas arose during the project and the workshops that could not be covered here. These included suggestions for next steps, including the extension of data donation to corporate data by means of data philanthropy schemes, and the addition of other data sources, such as health-related data collected by medical or lifestyle wearable devices. The latter raises important ethical issues beyond the scope of the present volume, such as the question of how to treat the digital remains of the dead (Öhman and Floridi 2018). Finally, the ethical code for PMDD proposed in this volume could eventually be extended to include donations made by living individuals, but for the reasons explained in the following chapters, we considered it ethically preferable to begin with deceased donations.

1.3   This Volume and Its Chapters

The book contains the proceedings of the two workshops held in Oxford, and some additional highly relevant contributions. It seeks to provide a timely analysis of the ethical use of existing personal medical data. The volume comprises four parts.

Part I seeks to conceptualise the ethics of medical data donation, by attempting to define what donation means in the context of data, and by identifying the key opportunities and ethical challenges of medical data donation.

Barbara Prainsack in "Data Donation: How to resist the iLeviathan" ascribes the distinctive characteristics of relationality, indirect reciprocity and simultaneity to data donation, as a specific type of transaction. She suggests that consideration of these characteristics could make data donation a strategy to counterbalance the overarching power of multinational enterprises. They have become 'a necessary monster' to which people submit their freedoms to in order to obtain other goods they consider essential.

In "Data Donation as Excercises of Sovereignty", Patrik Hummel, Matthias Braun and Peter Dabrock argue that data donations offer the potential to advance individual sovereignty, as they can generate social bonds, convey recognition and open up new options in social space. Articulating some of the difficulties associated with data donations, they call for thoughtful governance mechanisms and appropriate technological infrastructure design in response.

Philip J. Nickel in "The Ethics of Uncertainty for Data Subjects" discusses the practical uncertainties of modern data practices. He argues that significant endemic uncertainties undermine data subjects' interests in having grounds for trust in the institutions and organisations that control their data and proposes some possible ways of addressing this ethical problem.

Kerina H. Jones discusses the panoply of issues that may influence individuals' decisions with regard to data donation. In "Incongruities and Dilemmas in Data Donation: Juggling our 1s and 0s", she argues that although it would be unethical not to use donated medical data for the public good, it is crucial to acknowledge the conflicting beliefs and interests at play in data donation and which need to be carefully balanced.

In Part II, some of the key governance and regulatory challenges are discussed.

In her chapter, "Posthumous Medical Data Donation: The Case for a Regulatory Framework", Edina Harbinja outlines the most significant legal issues potentially affecting the donation of medical data after death and proposes how such a scheme would fit within the exiting legal framework governing health data.

Annie Sorbie in "Medical Data Donation, Consent and the Public Interest: A Gateway to Posthumous Data Use" suggests that in posthumous data donation, consent does not provide a 'magic bullet' and is only one aspect of a holistic governance regime. She argues that emphasis should be placed on the role of authorisation in this context.

Part III discusses the responsibility of all citizens to participate in medical data
donation and provides some examples for implementation.

In "The Personal Data is Political", Bastian Greshake Tzovaras and Athina
Tzovara use the examples of genetics and neuroscience to support their argument
that in order to achieve truly personalized medicine, datasets need to be sufficiently
diverse. They argue that this requires all of us to share our data for medical research
purposes.

Ernst Hafen, in his chapter "Personal-Data Cooperatives – A New Data
Governance Framework for Data Donations and Precision Health", explains one
way in which this may be achieved. Calling for a more active role of citizens in the
collection and management of personal data, he argues that data cooperatives are
the perfect match for the challenges associated with the use of personal data, as they
give democratic control to the citizen-owners.

In "Defining Data Donation After Death: Metadata, Directives, Guardians and
the Road to Big Consent", David Shaw argues that given some ethical concerns,
unconditional data donation may be premature and that a more cautious approach
involving preference-setting through data advance directives and requiring family
consent may be preferable as a first step.

Part IV concludes this volume with a discussion of the need for an ethical code for
PMDD and the introduction of such a code.

In "Enabling Posthumous Medical Data Donation: A Plea for the Ethical
Utilisation of Personal Health Data", Jenny Krutzinna, Mariarosaria Taddeo and
Luciano Floridi argue that personal medical data should be made available for sci-
entific research, by enabling and encouraging individuals to donate their medical
records once deceased through PMDD. They stress the need to develop an ethical
code for data donation to minimise the risks and conclude with the draft for such a
code.

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